REMARKS

The Examiner is thanked for the for the courtesies extended during an interview with the undersigned conducted by telephone on March 6, 2006. In the Interview Summary, the Examiner stated that "Mr. Brown discussed changing the term 'preventing' to 'inhibiting'. Mr. Brown may also point out in the specification that there are examples showing phytanic acid and its derivatives are effective in treating and inhibiting non-insulin dependent diabetes mellitus (Type II diabetes." (Paper No. 20060306.)

To make the record clear, we not that the term "preventing" was previously deleted in favor of "inhibiting" in the paper entitled Response to Final Office Action Pursuant to 37 CFR § 1.116 Including Amendment, mailed December 8, 2005. This amendment was made as the Examiner suggested in the Office Action dated October 27, 2005 to "overcome [the enablement] rejection." (Paper No. 20051025 at 4.)

Enablement Rejection

Claims 10-13 and 20-24 stand rejected solely under 35 USC § 112, first paragraph, on the asserted grounds that "[t]he level of experimentation needed to determine phytanic acid and its derivatives would be able to treat or inhibit non-insulin dependent diabetes mellitus is undue." (Paper No. 20060118 at 4.) In making the rejection, the Examiner asserted that the "claim(s) contains subject matter which was not described in the specification in such a way as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." (*Id.* at 2.)

To facilitate discussion of the present rejection, a brief summary of the pending enablement rejection follows. The enablement rejection was initially presented in the first Office Action on the merits (Paper No.: 20050224) dated March 1, 2005. In the Office Action, the Examiner rejected claims 10-13 under 35 USC § 112, first paragraph, on the asserted grounds that the specification "does not reasonably provide enablement for treating non-insulin dependent diabetes mellitus with a phytanic acid precursor or a derivative of phytanic acid or preventing non-insulin dependent diabetes mellitus with phytanic acid, a phytanic precursor, or a derivative of phytanic acid." (*Id.* at 3.) However, the Examiner expressly conceded that ***the specification is "enabling for treating non-insulin dependent diabetes mellitus with phytanic acid.***" (*Id.*) (Emphasis added.)

A Response to Office Action Including Amendment was filed July 29, 2005. The amendments deleted "phytanic acid precursor" from the claims and added claims 20-24, all depending from claim 10. The response included a Declaration under 37 CFR § 1.132 of Dr. Beat Flühmann, a co-inventor of the present application. (Attached as Exhibit A.) In the declaration, Dr. Flühmann concluded that "one of skill in the art would readily recognize that phytanic acid would be useful for treating ... non-insulin dependent diabetes mellitus ... [and] that administration to a human or an animal of an effective dose of a pharmaceutical composition or a dietary supplement containing phytanic acid ... or a derivative of phytanic acid would be effective to treat or prevent non-insulin dependent diabetes mellitus." (Declaration ¶38.)

On October 27, 2005, the Examiner issued a Office Action finally rejecting claims 10-13 and 20-24 solely under 35 USC § 112, first paragraph, on the asserted grounds that the specification "does not reasonably provide enablement for preventing non-insulin dependent diabetes mellitus with phytanic acid or a derivative of phytanic acid." (Paper No. 20051025 at 2.) (Emphasis added.) In making the rejection, the Examiner again expressly conceded that ***the specification is "enabling for treating non-insulin dependent diabetes mellitus with phytanic acid or a derivative of phytanic acid***." (*Id.*)

The Examiner suggested that "[t]o overcome this rejection, the applicants may wish to amend claim 10 by deleting the word "preventing" and replace with --inhibiting--." (*Id.* at 4.)

As noted previously, in the Response to Final Office Action Pursuant to 37 CFR § 1.116 Including Amendment, mailed December 8, 2005, claim 10 (the sole independent claim under examination) was amended in accordance with the Examiner's guidance to delete "preventing" and to recite "treating or inhibiting non-insulin dependent diabetes mellitus." With this amendment the rejection was rendered moot and should have been withdrawn.

The Present Office Action

In response to the Applicants' amendment, the Examiner withdrew the finality of the previous Office Action and issued the present Office Action, rejecting claims 10-13 and 20-24 solely under 35 USC § 112, first paragraph, on the asserted grounds that "specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims." (20060118 at 2.) The rejection is surprising in light of the Examiner's admission that the specification is "enabling for treating non-insulin dependent diabetes mellitus with phytanic acid or a derivative of phytanic acid." (Paper No. 20051025 at 2.)

For the following reasons, the rejection is traversed.

As is well settled, it is the Examiner's burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi,* 169 USPQ 367, 369 (CCPA 1971). To carry this burden, the Examiner must identify and clearly articulate the ***factual bases and supporting evidence*** that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue." MPEP § 2164.01 citing *in re Angstadt,* 190 USPQ 214, 219 (CCPA 1976).

Initially, we note that the rejection fails to make the requisite factual inquiry to support a conclusion that undue experimentation is required to make and/or use the claimed invention. Instead the Examiner offers only a conclusion without any evidence or reasoning to support the conclusion.

> No working examples showing phytanic acid or a derivative of phytanic acid treating or inhibiting non-insulin dependent diabetes mellitus. ... Applicants have failed to provide guidance as to how the instant composition or dietary supplement comprising phytanic acid and its derivatives will treat or inhibit non-insulin dependent diabetes mellitus. The level of experimentation needed to determine phytanic acid and it derivatives would be able to treat or inhibit non-insulin dependent diabetes mellitus is undue. Therefore, undue experimentation would be required to practice the invention

as it is claimed in its current scope. (Paper No. 20060118 at 4.)

An unsubstantiated conclusion, is not, and indeed cannot be, sufficient to support *a prima facie* case for lack of enablement. Absent the required ***factual*** analysis, it is respectfully submitted that the rejection should be withdrawn.

Moreover, as demonstrated by the declaration of Dr. Flühmann previously presented in this case, the specification contains disclosure that clearly enables the claims being prosecuted. According to Dr. Flühmann the specification is replete with disclosure that supports the conclusion that phytanic acid, at physiological concentrations, acts via both peroxisome proliferator-activated receptors (PPAR) α and γ to activate the transcription of a distinct pattern of genes that favors glucose uptake and can be used to manage insulin resistance. (*Id.*, ¶6.) As Dr. Flühmann states "[t]hese *in vitro* and *in vivo* results confirm what is disclosed in the specification, namely that phytanic acid produces a biochemical result, which prevents or mediates the metabolic abnormalities associated with NIDDM *in vivo*." *(Id)*

The Examples in the specification demonstrate that treatment with phytanic acid 1) increases the uptake of glucose in rat hepatocytes, 2) up regulates the production of the mRNA for various proteins related to glucose uptake (e.g., GLUT-1, GLUT-2, glucokinase, and PEPCK), and 3) reduces plasma insulin levels. (*Id.*, ¶9.) As Dr. Flühmann observes, the specification discloses that these results demonstrate that administration of phytanic acid and phytanic acid derivatives normalize and increase the glucose level without a concomitant risk of hypoglycemia and is thus "excellently suited for the treatment ... of diabetes mellitus." (*Id.*, ¶7.) Based on the disclosure in the specification and the relevant knowledge in the art, Dr. Flühmann concluded that "one

skilled in the art would readily recognize that phytanic acid would be useful for treating ... non-insulin dependent diabetes mellitus." (*Id.*, ¶38.)

We respectfully note that the PTO is required to consider Dr. Flühmann's expert declaration. To date, this has not been done. Thus, it is respectfully submitted that in light of Dr. Flühmann's expert comments explaining what is described in the specification and how one skilled in the art would have interpreted such disclosure, one must conclude that the specification clearly enables one of skill in the art to make and use the claimed invention. For this reason, it is respectfully submitted that rejection should be withdrawn.

Accordingly, for the reasons set forth above, withdrawal of the rejection and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 24, 2006.

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Respectfully submitted,

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